EXHIBIT U
Part 3

PAYMENT FOR ADMINISTRATION OF DRUGS

At present, Medicare generally pays a separate charge for administration of an injection (Medicare Carriers Manual, § 5202). The Manual specifies that the allowable charge should be $2, although some carriers may be paying a higher amount. Under HCFA's proposal, Medicare would no longer pay an injection administration fee if any other service (such as an office visit) was furnished at the same time as the injection.

In addition to the general codes for drug injections -- to which the Manual provision presumably applies -- the CPT establishes other codes for specialized types of injections. Among these are the codes for chemotherapy administration (CPT codes 96400-96549).

Under the proposal, HCFA would continue to pay a separate administration fee for those forms of chemotherapy considered to be procedures rather than injections. Thus, chemotherapy administered by infusion (CPT codes 96410, 96412, 96414, 96422, 96423, 96425) and the administration of chemotherapy into specialized body cavities (CPT codes 96440, 96445, 96450) would continue to be paid separately. However, there would no longer be a separate payment for chemotherapy administered intravenously by push technique (CPT codes 96408, 96420), or for subcutaneous or intramuscular injections of chemotherapy agents (CPT code 96400).

ASCO supports HCFA's recognition that a separate payment is generally appropriate for chemotherapy administration. Oncologists administering chemotherapeutic agents incur substantial practice costs beyond the overhead expenses of, for example, an internist's office. These extra costs include specialized equipment (such as special chairs for the patients undergoing chemotherapy and laminar flow hoods for mixing the chemotherapy agents), additional office space, specially trained oncology nurses, and special waste disposal costs. In addition, significant personnel time is needed for mixing and preparing the drugs and, especially in the case of infusions, for administering the drug. It would be totally inappropriate to regard these substantial drug administration costs as covered by the payment for an office visit, and HCFA properly proposes to continue the current practice of making a separate payment.

In our view, however, the proposal inappropriately excludes chemotherapy administered by push technique from this separate payment. It is true that injections by push take less time than injections by infusion, and the personnel cost is therefore reduced. The costs of chemotherapy administration by push, however, are in no way comparable to the costs of an ordinary intramuscular injection of a non-toxic drug, as the proposal seems to assume. Almost all of the costs incurred in connection with infusion injections are also present in the case of pushed injections, including the specialized equipment, nurses, and waste disposal. The only difference is the reduced time involved in the administration itself. The other costs remain substantial and would not properly be covered by assuming their inclusion in the office visit charge. Medicare should therefore continue to make a separate payment for chemotherapy injections by push technique (CPT codes 96408, 96420).

Medicare should also continue to pay separately for intramuscular or subcutaneous chemotherapy injections (CPT code 96400). Although not many chemotherapy drugs are administered in this fashion, these injections do involve additional overhead costs beyond the

costs incurred for non-toxic injections. For example, the common chemotherapy agent L-asparaginase is administered intramuscularly. This agent can require mixing, has significant potential side effects, and is subject to the special waste disposal requirements as other chemotherapy agents. Thus, HCFA should continue to pay separately for these types of chemotherapy injections.

Finally, we want to bring to HCFA's attention a potential problem in calculating the national average allowed charge for the chemotherapy administration codes. There is some variation in how the Medicare carriers use the codes where more than one chemotherapy agent is administered. Particularly in the case of pushed injections, some carriers allow reporting a code (e.g., 96408) for each drug used. This interpretation is consistent with advice given by the American Medical Association coding staff concerning pushed injections. Moreover, since multiple drugs result in greater overhead costs than a single drug, this coding method distinguishes the level of practice expenses incurred in various situations. The majority of Medicare carriers, however, require a code to be reported only once regardless of the number of drugs involved. Because the allowed charges in carrier areas where a code is reported for each drug can be significantly lower than in areas where the code is reported only once no matter how many drugs are used, it would not be appropriate simply to average all the allowed charges together. Charges should be adjusted before averaging so that they all represent the same service.

SUPPLIES

Oncologists use supplies extensively in connection with chemotherapy administration. These supplies include tubing and other equipment for intravenous injections, specialized needles, blood collection bottles, and other disposable items.

Under the proposed rules, Medicare would ordinarily not pay separately for supplies used in connection with physician services. Instead, supply costs would be considered covered by the practice expense component of the payment for physician services.

A. Allocation of Supply Payments

ASCO agrees in principle with the proposed approach of generally considering supply costs to be included in the payments for practice expenses. Thus, in the case of chemotherapy, it is reasonable for the chemotherapy administration codes to cover supply costs as well as the other expenses involved.

ASCO strongly opposes, however, the method by which HCFA is proposing to deal with supply costs in those carrier areas where supplies have traditionally been paid separately. The notice states that HCFA is considering allocating dollars currently paid for these supplies across practice expense relative values for all office-based procedures.

In our view, it would be highly unfair to allocate supply costs across all procedures. A number of carriers now pay separately for certain supplies ordinarily used in chemotherapy administration (e.g., infusion trays, intravenous tubes). Since these supplies are consistently used

in many chemotherapy administration procedures, ASCO does not object to a bundled payment that includes these supplies as well other technical aspects of the chemotherapy administration. Allocating current supply payments across all procedure codes, however, will dilute the impact of these costs and will thereby fail to establish a proper payment level for the bundled chemotherapy administration code.

Under the statute, the payment level for the chemotherapy administration codes will be based on national average allowed charges in 1991 for that service. Those carriers that have paid for chemotherapy supplies separately should bundle those supply costs into the chemotherapy administration charges in determining these amounts. Only in this manner will the payment amounts of the various carriers be comparable.

B. Separate Payment for Parenteral Hydration Products

The proposed regulation does not expressly discuss the proposed treatment of the fluids that are administered intravenously in connection with chemotherapy. These fluids are currently considered drugs for HCPCS coding purposes. We believe that most carriers pay for such fluids as drugs, although a few may treat them as supplies, for which they may or may not make separate payments.

Parenteral hydration fluids should be considered drugs and paid for in the same manner as other drugs, and we request that HCFA clarify this point in the final regulation. The use of fluids varies greatly depending on the type of chemotherapy used. Some drugs do not require hydration, while others necessitate the administration of substantial quantities of fluids. Because of this variability of an item of substantial cost, it would not be appropriate to bundle the costs in chemotherapy administration payments. Rather, separate payment should be made as in the case of any other drug.

C. Separate Payment for Certain Supplies

Certain supplies would be subject to separate payments under the proposal. These are identified in the notice as relatively expensive, disposable supplies used in connection with particular procedures (including lumbar puncture trays, venous access catheters, thoracentesis trays, and bone marrow aspiration trays, among others). These supplies would be paid separately only if they were used in a procedure that is routinely furnished in a hospital or ambulatory surgical center, as determined by HCFA. Payments for the supplies would be based on a nationally uniform fee schedule add-on.

ASCO supports this proposal to make separate payments for those supplies identified in the notice, and agrees that a nationally uniform payment amount is appropriate. However, it is important that the payment amount accurately reflect the actual costs of these supplies at any given time. HCFA apparently contemplates establishing the add-on payment at an amount exactly equal to the amount at which it believes the supplies can be purchased, as determined by surveys. We are concerned that the payment amount determined by these HCFA surveys will not necessarily reflect the actual supply costs faced by physicians due to price increases in supplies after the surveys are conducted. In order to adjust for these price increases, carriers should be

required to increase supply payments mid-year, if they determine that supply costs have increased.

MEDICAL VISITS AND CONSULTATIONS

ASCO supports HCFA's efforts to revise the visit and consultation codes in order to ensure uniform interpretation and allow for the use of appropriate relative values. We regret, however, that HCFA apparently plans to implement a series of new codes without affording an opportunity for public comment. Although we understand the time constraints involved, we urge HCFA to implement an appropriate notice and comment process that will allow full scrutiny of the new codes prior to their adoption.

ASCO is particularly concerned about the inclusion of time factors in the descriptors of the various visit codes. We believe that the time periods specified as being average for each level of service may not accurately reflect the actual time necessary for the oncology services involved. The lack of congruence between the content descriptors, which will actually govern the classification of services, and the supposedly average time period may provoke substantial controversy between carriers and physicians who perform the services more rapidly than the stated average time would suggest.

Although the definitions of the visit codes are far from complete, the early results confirm our concerns about use of the time factor. On January 23, 1991, the CPT Editorial Panel of the American Medical Association circulated to the CPT Advisory Committee its draft content descriptors, together with specialty-specific examples based on the vignettes and relative values determined by Hsiao. For example, the hematology/oncology vignette of "office visit for restaging of an established patient with new lymphadenopathy one year post therapy for lymphoma" was placed in level 5 (the highest level) of the series for established patients. Based on the content descriptor for level 5 and on the relative value for the vignette, this appears to be a correct classification. However, the estimated average face-to-face time for this level of service is stated to be 40 minutes -- a time period that would significantly exceed the time that an oncologist would ordinarily take to treat the patient described in the vignette.

Because the time estimates appear to be inaccurate, at least as they relate to the types of services performed by oncologists, ASCO urges HCFA not to include any time references in the content descriptors until they have been thoroughly verified and shown to be applicable to the kind of services performed by subspecialties such as medical oncology.

SERVICES FOR WHICH RELATIVE VALUES HAVE NOT BEEN ANNOUNCED

It is difficult to evaluate the impact on oncologists of the proposed fee schedule because it fails to set forth a relative value for most of the services performed by them. In addition to leaving unresolved the final form of the visit and consultation codes, the proposed fee schedule does not include proposed relative values for the chemotherapy administration codes (96400-96549) or for bone marrow aspiration (85095) -- procedures commonly performed by oncologists.

We assume that HCFA intends that the chemotherapy administration codes will be based only on practice expenses and malpractice costs and that the relative value for bone marrow aspiration will be developed in the Hsiao Phase III study. We urge HCFA to make available adequate documentation as to how it develops the fee schedule amounts for these codes to allow proper evaluation.

ASCO should have an opportunity to comment on these relative values and to have HCFA consider our comments in deciding on the final relative values. ASCO requests that HCFA make these important relative values known informally to ASCO as soon as possible, since they were not available for review during the public comment period. In addition, we agree with the statement in the proposal that such relative values should be interim in nature and subject to revision after a formal period of public comment.

MINOR SURGERY AND NONINCISIONAL PROCEDURES

The proposal contains new procedures for dealing with minor surgeries designated by a "star" in the CPT code book and with the "scopies" listed in the surgery section of CPT. In the case of the starred procedures, CPT instructs physicians to bill separately for the procedure and for any associated services or visits (i.e., a global charge is not used). CPT does not specify whether visit charges are appropriate in addition to "scopy" charges.

Under the HCFA proposal, no visit charge would generally be allowed in addition to the charge for the minor surgery or the "scopy" unless a documented, separately identifiable service is furnished. Also, the proposal would require the charge for the procedure to include all post-operative services "related to recovery from the procedure" for a period of 30 days. The minor surgeries and "scopies" that would be included in this policy would be identified in carrier instructions.

ASCO is concerned about this proposal. Some forms of chemotherapy require thoracentesis, paracentesis, or lumbar puncture (which are starred procedures) for their administration. As we understand HCFA's plans, HCFA will adopt a uniform national policy that the chemotherapy administration codes will represent practice expenses only and the physician's services associated with chemotherapy will be covered by a visit code (or a new chemotherapy management code). Thus, when the chemotherapy involves a thoracentesis, paracentesis, or lumbar puncture, there would ordinarily be a visit code accompanying that procedure code.

We believe that it would not be appropriate to require the submission of special documentation justifying the visit charge simply because a thoracentesis, paracentesis, or lumbar puncture was also part of the chemotherapy service furnished. A visit charge will typically accompany a chemotherapy administration charge and that visit charge should not become suspect simply because a lumbar puncture or similar procedure was part of the chemotherapy. Therefore, if HCFA implements this policy concerning visits and starred procedures, carrier instructions should specify that special documentation is not required for a visit charge accompanying a thoracentesis, paracentesis, or lumbar puncture if the procedure was part of chemotherapy administration.

ASCO also questions the proposal that all services "related to recovery" from a starred procedure and performed within 30 days would be considered included in the payment for the starred procedure. The test of what is "related to recovery" is not defined in the proposal except through a single example (removal of sutures). Although the example provided is clear, we believe that the issue of what is "related to recovery" may in many circumstances be much more ambiguous and subject to dispute. There does not seem to be good reason for departing from existing policy on charges for minor procedures, and ASCO urges that the proposed change not be adopted.

PROVIDER-BASED PHYSICIANS

ASCO supports the proposed termination of restrictions on payments to teaching physicians and other physicians who furnish services in hospitals, including the elimination of compensation-related customary charges. We agree with HCFA that Medicare payment for all physicians should be based on the fee schedule without additional limitations.